Appl. No. : 09/636,278
Filed : August 10, 2000

AMENDMENTS TO THE SPECIFICATION

Please amend the paragraph beginning on Page 1, line 4 as follows:

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This application is a continuation in part of an earlier filed application (Serial No. 08/650,464 filed May 20, 1996, now abandoned), which is in turn a continuation in part of an application (Serial No. 08/464,579) filed June 6, 1995, now U.S. Patent No. 5,833,650.

Please amend the paragraph beginning on Page 1, line 7 as follows:

Details regarding the centering of intravascular devices used in radiation treatment are described in Assignee's co-pending U.S. Application Serial No. 09/026103, now U.S. Patent No. 6,338,709~~______, filed on the same date herewith (Atty. Docket No. PERCUS.032A)~~, entitled Intravascular Radiation Therapy Device, and Method of Use, which is hereby incorporated by reference.

Please amend the paragraph beginning on Page 6, line 4 as follows:

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Self-expanding sealing mechanism 666 is mounted on the distal extremity 654. This self-expanding sealing mechanism 666 can take any suitable form. For example, as shown it can consist of a braided structure 667 formed of a suitable shape memory material such as a nickel titanium alloy that will attempt to expand to a predetermined shape memory. Other than shape memory materials, other materials such as stainless steel, ELGILOY®~~Elgiloy~~™, titanium or other materials can be utilized in the braid 667 as long as they have the capability of expanding when the self-expanding seal mechanism is released. Also it should be appreciated that the self-expanding seal mechanism 666 can be comprised of an absorbent material which when it absorbs saline or blood expands to form a seal. Such seals can be readily accomplished because it is only necessary to form a seal of approximately 1.5 psi to prevent small particles from moving downstream.

Please amend the paragraph beginning on Page 6, line 15 as follows:

In order to prevent abrasion of a vessel, it is desirable to cover the braided structure 667 with a covering 668 of a suitable material such as a polymer or a biocompatible coating which extends over the braided structure 667 and which moves with the braided structure 667 as it expands and contracts. The polymer can be of a suitable material such as silicone, C-FLEX®,~~C-~~

C2 ~~flex,~~ polyethylene or PET which would form a good sealing engagement with the wall of the artery. The covering 668 may be perforated to allow perfusion.

~~Please amend the~~ paragraph beginning on Page ~~8~~ 9, line ~~9~~ 2 as follows:

C3 Another embodiment using a braided structure is shown schematically in FIG. 5, in which a flexible elongate member 20 is disposed within a second elongate member 24 such as a hypotube. A self expanding mechanism 28 such as a braided structure is secured to the distal end of the elongate member 20, preferably within an indentation 32 of member 20. The braided structure 28 is only partially encapsulated by a preferably elastomeric membrane 36 that makes a seal with the patient's vessel 40. (Alternatively, a coating such as a polymeric coating may be used in place of the membranes disclosed herein.) In this and the other embodiments, adhesive may be used to secure the self-expanding mechanism 28 and the membrane 36 to the elongate member 20. In the embodiment of FIG. 5, the braided structure 28 and membrane 36 are designed to be asymmetrical, with more material being concentrated at the proximal side of the structure 28. The braids of the embodiments disclosed herein may be stainless steel 304 or 400, superelastic or heat activated, shape-memory alloy, such as nitinol ~~Nitinol~~, an iron base shape memory alloy, or a polymer base, such as polyethylene or polypropylene. They may be constructed, for example, by using standard equipment such as a braider.

Please amend the paragraph beginning on Page ~~9~~ 10, line ~~15~~ 10 as follows:

C4 Alternative self-expanding media are shown in FIGS. 8 and 9. In FIGS. 8 and 9, a self-expanding filter-like mesh 60 and a self-expanding slotted tube 72, respectively, are surrounded by a membrane 62 that is preferably elastomeric. The filter-like mesh 60 (or slotted tube 72) and membrane 62 are bonded or otherwise secured to a flexible elongate member 64, e.g., to an indentation therein. As with the other self-expanding media disclosed herein, the filter-like mesh 60 (or slotted tube 72) expands from its unexpanded state when the flexible elongate member 64 is pushed through a second elongate member 66, or alternatively, when the second elongate member 66 is retracted over the first elongate member 64. The filter-like mesh 60 (or slotted tube 72) then expands so that the membrane 62 forms a seal with the surrounding vessel 68. A guidewire tip 70 aids in guiding the device through the vessel 68. The filter-like mesh 60 and slotted tube 72 are of a

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suitable shape memory material such as nitinol ~~Nitinol~~ or (304 or 400) stainless steel. The filter-like mesh 60 is fibrous in nature, being somewhat analogous to steel wool. The slotted tube 72 has a lattice-like appearance. The slotted tube 72 may be constructed, for example, by irradiating a thin-walled tube with a laser beam to form holes in the tube in the shape of polygons such as oblong quadrilaterals. An unexpanded, slotted tube 74 is shown in FIG. 10.

Please amend the paragraph beginning on Page ~~10~~ 11, line ~~16~~ 14 as follows:

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Another embodiment that employs a self-expanding medium is shown in FIG. 13, in which a plurality of ribbons 100 make contact with a membrane 102 while they expand to urge the membrane towards the wall of the vessel 104 where it makes a seal. The ribbons 100 of this embodiment are preferably secured to a first elongate member 106 at both ends of the ribbons, by, for example, gluing them in place. The ribbons may be 0.001-0.004" x 0.005-0.020" x 0.25-1.0" strips of shape memory alloy, such as nitinol, ~~Nitinol,~~ stainless steel, or ELGILOY® ~~Elgiloy™~~ which expand when urged out of the second elongate member 108. A guidewire tip 110 may be used for guiding the device through the vessel and is preferably secured to the distal end of the first elongate member 106.

Please amend the paragraph beginning on Page ~~10~~ 11, line ~~25~~ 23 as follows:

FIG. 14 illustrates an embodiment similar to the one in FIG. 13, in which ribs 120 such as wires form a series of semicircular arcs when they expand. The ribs 120 are surrounded by a membrane 122 that expands with the ribs to form a seal with the vessel 124. The number of ribs 120 is preferably at least three. The ribs 120 are preferably attached directly to a first elongate member 124 that is surrounded by a second elongate member 126. The ribs 120 themselves are preferably made of a shape memory material such as nitinol ~~Nitinol~~ or stainless steel. A guidewire tip 128 aids in guiding the device through the vessel 130.

Please amend the paragraph beginning on Page 11, line 6 as follows:

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FIGS. 12A and 12B illustrate how electrical means can be used to generate heat to expand an expansion member. A first elongate member 82′ (and a coil 80′ which adjoins it, coil 80′ and member 82′ being similar to their unprimed counterparts) is preferably made of heat activated

shape memory alloy, such as nitinol, ~~Nitinol,~~ an iron base shape memory alloy, or another material that expands when exposed to heat. As shown in FIG. 12A, low profile, low resistivity electrical lines 81 and 83 preferably pass either through or along the second elongate member 86 and are attached (e.g., soldered) to the first elongate member 82′ on either side of the coil 80′. When current is applied through the electrical lines 81 and 83 (the power supply is not shown but is preferably outside the patient), the coil 80′ heats up through resistive heating, and the coil expands to urge the membrane 84 to contact the vessel wall 90. Alternatively, as shown in FIG. 12B, the first elongate member 82′ may have a coating 85 of gold or silver. In this embodiment, the coated elongate member 82′ is used to pass current (with most of the current preferably being carried by the coating 85, so that most of the energy is deposited in the coil 80′), with the circuit being completed with a low resistivity wire 87 that is preferably connected (e.g., soldered) to either the second elongate member 86 or the sheath 94. This principle of resistive heating to expand a expansion member can be applied to the other embodiments disclosed herein as well.

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Please amend the paragraph beginning on Page 11, line 23 as follows:

FIGS. 13A, 13B, and 13C illustrate how heat transfer using a liquid can deploy an expansion member. The ribbons 100′ are preferably made of heat activated shape memory alloy, such as nitinol, ~~Nitinol,~~ an iron base shape memory alloy, or another material that expands when exposed to heat. In the embodiment of FIG. 13A, a warm saline solution 107 is passed between the first and second elongate members 106 and 108 and then over the membrane 102, so that heat is transferred to the ribbons 100′. As the ribbons 100′ heat up, they expand, thereby urging the membrane 102 against the vessel wall 104. As illustrated in FIG. 13B, the warm saline solution 107 may also be passed through the first elongate member 106 and then through holes 109 in member 106 so that the saline solution 107 more directly transfers heat to the ribbons 100′. In this embodiment, one or more holes 111 in the membrane 102 (distal to where the seal with the vessel wall 104 is made) may be used to allow the saline solution 107 to flow away beyond the ribbons 100′ after heat transfer to the ribbons occurs. As illustrated in FIG. 13C, the saline solution 107 may also be passed through one or more closed loop coils or lumens 113 within the first elongate member 106. In this way, the ribbons 100′ and the patient's blood are not exposed directly to any solution. Using

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heat transfer can also be applied to the other embodiments disclosed herein, provided the expansion member is suitably constructed.

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